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130.900: Standards for Operation of Hospital-based Cardiac Catheterization Services

105 CMR 130.900 through 130.982 set forth standards for the operation of hospital-based adult cardiac catheterization laboratories. Cardiac catheterization procedures shall not be performed in a satellite facility or a freestanding clinic. Any hospital wishing to provide cardiac catheterization services shall request prior approval from the Department. Any hospital wishing to perform cardiac catheterization procedures on pediatric patients must apply to the Department for approval of a special project, as described under 105 CMR 130.051. The application process for the pediatric cardiac catheterization service special project is described in 105 CMR 130.921.

130.910: Definitions

Cardiac Catheterization Services means diagnostic and therapeutic services, other than cardiac surgery, which are not usually performed at the patient's bedside and which involve the introduction of physical objects (such as catheters) into the heart, its chambers, the pericardium, or the great vessels proximal to the heart. Examples of cardiac catheterization services are right heart and left heart cardiac catheterization, coronary angiography, ventriculography, and percutaneous coronary interventions. Excluded from this definition are: bedside cardiac and pulmonary artery catheterization using floating and/or indwelling catheters; the implantation, repair, and replacement of cardiac pacemaker devices; and cardiac radionuclide scanning procedures that do not require the use of the cardiac catheterization laboratory.

Electrophysiology Studies (EPS) means the recording of intracardiac electrogram, atrial or ventricular stimulation, intracardiac mapping or cardiac ablation.

Primary Operator means a physician who is scrubbed and provides hands-on participation in and has primary responsibility for all aspects of the cardiac catheterization service procedures. There is one primary operator per case. However, for the purpose of counting operator volume pursuant to 105 CMR 130.900 through 130.982, in a training situation a fellow and the attending physician may both be considered the primary operator for the case.

130.915: Department Approval to Provide Adult Cardiac Catheterization Services

(A) A hospital licensed pursuant to M.G.L. c. 111, § 51 that intends to provide cardiac catheterization services shall apply for and receive approval from the Department in order to provide cardiac catheterization services. The Department shall grant its approval if it finds that the hospital meets the standards and requirements in 105 CMR 130.900 through 130.982 for operating a cardiac catheterization laboratory. Upon determination that the hospital meets the relevant requirements, the Department shall cause the license issued to a hospital pursuant to 105 CMR 130.120 to indicate that the licensee is authorized to provide cardiac catheterization services as a specific service of the hospital. All cardiac catheterization laboratories shall obtain Department approval pursuant to 105 CMR 130.900 through 130.982 prior to operating such a program.

(B) A mobile cardiac catheterization service shall be organized and coordinated by a hospital licensed or operated by the Commonwealth pursuant to M.G.L. c. 111, § 51 (the sponsor or lead hospital), that has operated a fixed site cardiac catheterization service for at least one year immediately prior to filing an application, and shall meet all licensure requirements. Upon

determination that the sponsor and host site hospitals meet the relevant requirements, the Department shall cause the license issued to the sponsor and host site hospitals pursuant to 105 CMR 130.120 to indicate that the licensees are authorized to provide mobile cardiac catheterization services as a specific service of the hospital.

#### 130.920: Initial Application to Provide Adult Cardiac Catheterization Services

(A) As directed by the Department, each hospital seeking to provide cardiac catheterization services shall submit an application that documents how the hospital will meet the cardiac catheterization services standards. Every application shall be notarized and signed under the pains and penalties of perjury by the applicant or a person authorized to act on behalf of the applicant.

(B) Applicants shall list the specific procedures that are proposed to be provided by the cardiac catheterization service.

(C) Applicants for cardiac catheterization services shall document how the service will meet the facility volume minimums within the two year time frame required in 105 CMR 130.935: Minimum Workload Requirements.

#### 130.921: Application to Provide Pediatric Cardiac Catheterization Services (Special Project)

(A) Any hospital that intends to provide pediatric cardiac catheterization services must request and receive from the Department written special project approval to provide pediatric cardiac catheterization services. Applicants should submit a written request to the Department. Pediatric cardiac catheterization procedures shall not be performed by a mobile cardiac catheterization service.

(B) All applicants shall at a minimum have the following:

- (1) a licensed Level III pediatric service, and
- (2) Determination of Need approval to perform open heart surgery.

#### 130.922: Timing of Application

After the initial licensure of the cardiac catheterization service, the hospital shall reapply for licensure of the cardiac catheterization service each time that it applies for renewal of its hospital license.

#### 130.924: Evaluation of Application

(A) The Department shall not approve an initial application to provide cardiac catheterization services unless the Commissioner or his designee has conducted an inspection or other investigation of the facility and has determined that the applicant complies with the requirements of 105 CMR 130.900 through 130.982.

(B) Applicants shall have demonstrated satisfactorily to the Department that the facility volume minimums will be met within 24 months of initial licensure.

#### 130.926: Issuance of an Amended Hospital License

Upon approval of the application to provide cardiac catheterization services, the Department shall issue an amended hospital license which indicates that cardiac catheterization is an approved service provided by the hospital.

#### 130.930: Establishment of Invasive Cardiac Services Advisory Committee

The Department shall establish an Invasive Cardiac Services Advisory Committee (ICSAC or the Committee) to advise the Department on issues related to invasive diagnostic and therapeutic cardiac services licensed by the Department. The Committee's membership shall be multidisciplinary and shall include but not be limited to physicians and nurses who are clinical experts in the field of cardiac catheterization, cardiac surgery and electrophysiology studies, hospital administrators and consumers. The committee shall be representative of the geographical areas of the Commonwealth and of community and tertiary hospitals.

#### 130.935: Minimum Workload Requirements

(A) Each cardiac catheterization service that performs only diagnostic procedures shall maintain a minimum caseload volume of 300 procedures per year.

(1) Any cardiac catheterization service providing fewer than 300 procedures per year shall, within 30 days of the end of the Department's fiscal year reporting period, submit to the Department a copy of the previous year's Quality Assessment and Performance Improvement (QAPI) quarterly reports required under 105 CMR 130.965(E).

(2) In addition to the requirements of 105 CMR 130.935 (A)(1), any cardiac catheterization service providing fewer than 150 procedures per year shall, within 30 days of the end of the Department's fiscal year reporting period, request a review of the catheterization service by an appropriately qualified professional peer review organization or individual(s) approved by the Department. Any physician conducting the peer review shall not have a practice based in Massachusetts and shall certify that he/she does not have any conflict of interest regarding the hospital and physicians to be reviewed.

The results of the review shall be submitted to the Department within ten days of receipt.

(3) Based on a review of the QAPI reports and, if applicable, the results of the assessment of the quality of the cardiac catheterization service by an appropriately qualified peer review organization or individual(s) approved by the Department, the Department shall determine whether a facility will continue to be licensed and, if applicable, subject to any conditions determined to be appropriate.

(4) New services shall reach the minimum number of procedures within 24 months of licensure of the service.

(5) For the purposes of measuring facility volume, a mobile cardiac catheterization service may aggregate the facility volume of participating hospitals.

(B) Cardiac catheterization services that perform therapeutic as well as diagnostic catheterizations shall perform a minimum of 600 catheterization procedures per year, of which 200 procedures shall be therapeutic.

(1) Any service performing therapeutic as well as diagnostic catheterizations that performs less than the volume minimums shall within 30 days of the end of the Department's fiscal year reporting period:

- (a) submit to the Department a copy of the previous year's Quality Assessment and Performance Improvement (QAPI) quarterly reports required under 105 CMR 130.965(E); and
  - (b) request a review of the catheterization service by an appropriately qualified professional peer review organization or individual(s) approved by the Department. Any physician conducting the peer review shall not have a practice based in Massachusetts and shall certify that he/she does not have any conflict of interest regarding the hospital and physicians to be reviewed.
- (2) The results of the review shall be submitted to the Department within ten days of receipt.
- (3) Based on a review of the QAPI and the results of the assessment of the quality of the cardiac catheterization service by an appropriately qualified professional peer review organization or individual(s) approved by the Department, the Department shall determine whether a facility will continue to be licensed and, if applicable, subject to any conditions determined to be appropriate.
- (4) New services providing diagnostic and therapeutic catheterizations shall reach the minimum number of procedures within 24 months of licensure of the service.

(C) If a hospital is required to submit its quarterly reports of the QAPI under 105 CMR 130.935 (A) or (B), the hospital shall subsequently continue to submit the quarterly reports of the QAPI to the Department for review each quarter until the hospital receives a notice from the Department to discontinue submission of the reports.

#### 130.940: Staff

(A) The hospital, or in the case of a mobile cardiac catheterization service, the sponsor or lead hospital, shall designate a licensed physician director who shall have responsibility for the cardiac catheterization service. The physician shall be board certified in cardiovascular disease. However, licensed physicians acting as the physician director of existing cardiac catheterization services as of July 25, 1997 who are not board certified in cardiovascular disease but who meet all other requirements in 105 CMR 130.900 through 130.982, shall be grandfathered. The physician director shall have training and experience in cardiac catheterization.

(1) The physician director of a cardiac catheterization service that performs therapeutic procedures shall be board certified in interventional cardiology. Experienced interventionalists who performed interventional procedures prior to 1998 and/or completed training prior to 1998 and did not seek board certification prior to 2003 are exempt from the board certification in interventional cardiology requirement, but must document that their volume and outcomes meet accepted national standards.

The physician director of a cardiac catheterization service that performs therapeutic procedures who is not board certified in interventional cardiology may meet the requirement of 105 CMR 130.940(A) by appointing a director of interventional cardiology who is board certified in interventional cardiology to assist with oversight.

(2) A hospital that performs diagnostic and interventional/therapeutic electrophysiology procedures (excluding those cardiac catheterization services that only implant pacemakers and perform no other electrophysiology procedures), shall designate a licensed physician director of electrophysiology services who is board certified in clinical cardiac electrophysiology (CCEP) and who has five years of post-fellowship experience and documented skill in performing electrophysiology procedures.

Any physician director of electrophysiology services who was in the position on February 11, 2009 but who does not meet the five year post-fellowship experience requirement shall be grandfathered regarding that five year requirement.

(B) (1) Prior to designation as physician director, the physician director of a catheterization service that performs only diagnostic catheterization procedures shall have had at least five years post-fellowship experience in performing cardiac catheterization procedures, including a minimum of 250 procedures in which he/she served as primary operator, and documented skill in performing cardiac catheterization procedures.

(2) Prior to designation as physician director, the **director of a cardiac catheterization service that performs therapeutic procedures** shall have at least five years post-fellowship experience in performing cardiac catheterization procedures, including at least 500 therapeutic cardiac catheterization procedures in which he/she served as primary operator, and documented skill in performing cardiac catheterization procedures.

(C) The cardiac catheterization service and EPS, if applicable, physician director(s) shall be responsible for at least the following:

- (1) Development and implementation of policies and procedures.
- (2) Development of patient selection and exclusion criteria based on nationally accepted published guidelines of the American College of Cardiology/American Heart Association and the Heart Rhythm Society.
- (3) Establishment and monitoring of quality control standards (including morbidity and mortality) for the cardiac catheterization/EPS laboratory and staff, including the development and implementation of the quality assessment and performance improvement program.
- (4) Supervision and training of all personnel, including in-service training and continuing education.
- (5) Procurement of equipment and supplies.
- (6) Proper safety, function, maintenance and calibration of all equipment.
- (7) Patient scheduling.
- (8) Maintenance of records of all hemodynamic angiographic and other diagnostic and therapeutic procedures performed.
- (9) Review and recommendations regarding the granting of physician privileges in cardiac catheterization service/EPS procedures.
- (10) Production of regular reports of cardiac catheterization/EPS laboratory activity and collection of pertinent patient data.

(D) The physician director may delegate to appropriate staff the activities related to the responsibilities listed in 105 CMR 130.940(C)(1) through (10).

(E) The physician director for a mobile cardiac catheterization service shall designate a clinically trained Program Manager at each participating hospital site to coordinate the activities of the cardiac catheterization service, in collaboration with the host hospital's Directors of Medicine, Nursing, Medical Records, Pharmacy, Laboratory, Radiology Services, and Infection Control.

(F) The physician director, with the hospital administration, or in the case of a mobile cardiac catheterization service, with the sponsor or lead hospital and host sites' administrations, shall establish criteria for granting privileges to licensed physicians to perform cardiac catheterization

procedures and shall review and make recommendations regarding the applications for those privileges. Privileges shall be granted for one year. Each physician must apply for and be awarded privileges on a yearly basis. Renewal of privileges shall be contingent upon results of appropriateness, technical quality, review of patient outcomes and other quality assurance information for all procedures. The review shall include an assessment of procedure volume for consistency with recommended minimum volume(s) in American College of Cardiology/American Heart Association and Heart Rhythm Society guidelines, as applicable, for maintaining competency in performing procedures.

(G) Each cardiac catheterization service, and in the case of a mobile cardiac catheterization service each participating hospital site, shall have on staff at least two physicians who are board certified in cardiovascular disease. Each physician who performs cardiac catheterization/EPS procedures shall be a fully accredited member of the hospital staff. Criteria for privileges shall at a minimum ensure the following:

(1) After July 25, 1997, physicians who are granted privileges to perform cardiac catheterization procedures as primary operator shall have had a minimum of eight months training in a cardiac catheterization laboratory during which time the physician performed a minimum of 300 diagnostic procedures.

(2)(a) Physicians seeking initial privileges to perform cardiac catheterization and/or EPS procedures who completed their training more than 12 months prior to seeking privileges and who do not have cardiac catheterization and/or EPS privileges at any other hospital shall meet the supervised retraining standards set by the physician director to ensure competency to perform the procedures.

(b) The retraining standards shall ensure that an individualized plan is developed for each physician that includes but is not limited to a minimum number of procedural observations, assistance at procedures and independently performed procedures to be completed by the physician. The plan, compliance with the plan, and the evaluation of physician competency shall be documented in the physician credential file.

(3) Physicians who perform percutaneous coronary interventions (PCI) shall have additional experience as the primary operator in a minimum of 250 PCI procedures, and shall be board certified in interventional cardiology.

(a) Physicians who are within 12 months after completion of a fellowship in interventional cardiology, while awaiting board certification may perform PCI procedures under the supervision of a physician who is board certified in interventional cardiology and performs more than 125 procedures per year, until he/she passes the board certification exam.

(b) Experienced interventionalists who performed interventional procedures prior to 1998 and/or completed their training before 1998 and did not seek board certification prior to 2003 are exempt from the board certification in interventional cardiology requirement, but must document that their procedural volume and outcomes meet accepted national standards.

(4) All physicians who perform percutaneous coronary interventions shall annually perform a minimum of 75 PCI procedures per year, consistent with the national guidelines adopted by the American College of Cardiology/American Heart Association.

(a) In a hospital where this volume minimum is not met, the physician director shall take measures acceptable to the Department to ensure the quality of the interventional procedures. This may include, but is not limited to, the establishment of a mentoring relationship between a physician(s) whose volume is less than 75 PCI procedures per



year and a highly experienced and skilled operator performing more than 150 PCI procedures per year.

If an operator performs PCI procedures at more than one hospital and does not meet the total volume minimum, the physician directors at each site at which the operator performs PCI procedures shall consult and collaborate with each other to establish measures acceptable to the Department to ensure the quality of the interventional procedures.

(b) An assessment of all mentoring relationships or other measures taken to assure quality of individual operator performance shall be included in the quarterly QAPI reports required under 105 CMR 130.965(E).

(H) At least two persons shall assist the physician during the performance of all cardiac catheterization procedures. At least one assistant shall be clinically trained (either a Registered Nurse, Nurse Practitioner or Physician Assistant).

(1) Personnel shall operate within the scope of practice as defined by the appropriate licensing and/or certifying board. These personnel shall be trained and experienced in the use of all appropriate instruments and equipment.

(2) A mobile cardiac catheterization service shall use a staffing team that travels to each site.

(I) Appropriate staff shall be available to ensure all electronic and mechanical equipment is regularly checked and maintained in safe working order.

(J) A physician who has medical staff privileges in vascular surgery shall be available for consultation to the cardiac catheterization service staff consistent with written guidelines developed by the hospital.

(K) An individual qualified under the provisions of 105 CMR 120.020: Registration of Radiation Machine Facilities and Services shall be available for consultation for monitoring radiation safety for patients and personnel consistent with written guidelines developed by the hospital.

(L) All members of the cardiac catheterization/EPS team shall maintain current certification in advanced cardiac life support.

(M) Hospitals participating in a mobile cardiac catheterization service shall, in collaboration with the appropriate tertiary facility, as required under 105 CMR 130.975(A), develop and implement initial and ongoing teaching, training and evaluation of participating hospital staff in the pre- and post-procedure care of cardiac catheterization patients.

#### 130.950: Equipment and Supplies

Each cardiac catheterization service shall include at least the following:

(A) X-ray tube.

(B) Image intensifier or digital acquisition unit.

(C) Pulse generator.

(D) Collimator.

(E) TV system.

(F) Image processor.

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(G) Data transfer.

(H) Data storage (archival system).

- (I) Monitoring and recording equipment.
- (J) Pressure transducers.
- (K) Equipment for determining cardiac output.
- (L) Equipment for determining oxygen saturation, hemoglobin, blood gas analysis and pH.
- (M) Appropriate cardiac catheters and accessory equipment.
- (N) Resuscitation equipment and medications.
- (O) Intra-aortic balloon pump located within the hospital and available to the laboratory. For hospitals without cardiac surgery services, an intra-aortic balloon pump designed for ambulance transport. At a minimum, quarterly in-service training shall be performed with this equipment to ensure maintenance of staff skills.

#### 130.955: Supportive Diagnostic Services

Each hospital that provides cardiac catheterization services, and in the case of a mobile cardiac catheterization laboratory, each participating hospital site, shall provide access to: services for hematology and coagulation disorders; electrocardiography; diagnostic radiology; clinical pathology; nuclear medicine and nuclear cardiology; doppler echocardiography; pulmonary function testing; microbiology; exercise stress testing; and cardiac pacemaker and defibrillator assessment.

#### 130.960: Space

(A) A cardiac catheterization/EPs laboratory shall meet the cardiac catheterization laboratory standards in the current edition of *Guidelines for Design and Construction of Health Care Facilities* of the American Institute of Architects, as referenced in 105 CMR 130.107, and shall include provisions for each of the following:

- (1) Control, monitoring and recording equipment.
- (2) X-ray power and controls.
- (3) Work room.
- (4) Dressing area for staff.
- (5) Dressing area for outpatients.
- (6) Patient preparation, holding, and recovery areas.

The recovery area must be directly accessible from the procedure room and designed according to the standards applicable to recovery areas for ambulatory surgery from the *Guidelines for Design and Construction of Health Care Facilities* referenced in 105 CMR 130.960(A).

- (7) Waiting area and toilet room.
- (8) Storage area for supplies and medications.

(B) Cardiac catheterization laboratory space renovated or constructed after July 25, 1997 shall include a minimum floor area of 500 square feet for the procedure room.

(C) A mobile cardiac catheterization laboratory shall meet, in addition to the general cardiac catheterization laboratory standards in the American Institute of Architects' (AIA) guidelines cited in 105 CMR 130.960(A), the AIA standards for mobile units.

- (1) Each mobile cardiac catheterization laboratory site shall provide a temperature-controlled connection to the hospital.
- (2) Each mobile cardiac catheterization laboratory site shall provide safeguards to ensure protection of the mobile van (e.g., barriers, restricted traffic flow).

#### 130.962: Assurance of Continuity of Care



Each hospital must develop and implement policies and procedures that assure the continuity of the patient care, from the pre-catheterization teaching and obtaining of written consent through post-procedure care and discharge.

### 130.965: In-house Evaluation of Quality

(A) Each cardiac catheterization/EPS service shall establish and maintain an effective, ongoing, data-driven, quality assessment and performance improvement (QAPI) program for all catheterization procedures, including electrophysiology procedures, if applicable, that focuses on patient outcomes while assessing individual operator clinical proficiency as well as overall laboratory safety and efficiency.

(B) The hospital, through its QAPI program, shall:

- (1) Identify indicators, based on nationally accepted standards, that reflect the quality of care and patient safety,
- (2) Collect and maintain data pertaining to these indicators in a systematic manner,
- (3) Perform statistical analyses of the results for comparison with nationally accepted quality indicator benchmarks,
- (4) Prepare reports to document comparison results and identify areas for improvement, and
- (5) Develop an approach to implement quality improvement efforts and problem solving that includes feedback for catheterization service staff on the effectiveness of the solutions and/or triggers further opportunities for improvement.

(C) The program shall include but not be limited to assessments of the following:

- (1) Appropriate patient selection (according to pre-established selection criteria, consistent with nationally accepted standards);
- (2) The appropriateness of each cardiac catheterization/EPS procedure;
- (3) Technical quality of the catheterization/EPS studies;
- (4) Diagnostic accuracy and completeness of studies;
- (5) All catheterization/EPS procedure-related complications and adverse outcomes (including infections), during the patient's hospital stay or 24 hours post procedure, whichever is longer;
- (6) Number of cases requiring interhospital transfer and the reason for transfer;
- (7) Laboratory diagnostic and therapeutic procedure volume;
- (8) Physician therapeutic procedure volumes, including an assessment of all mentoring relationships established or other measures taken pursuant to 105 CMR 130.940 (G)(4)(a), if applicable;
- (9) The number/percent of diagnostic cardiac catheterization procedures determined to be normal (i.e., no disease or physiologically insignificant coronary stenoses);
- (10) Processes and criteria for staff credentialing;
- (11) Ongoing clinical staff training and education;
- (12) Patient satisfaction; and
- (13) Outcomes in comparison to national benchmarks.

Each cardiac catheterization service shall participate in a national data registry to help benchmark results and track complications.

(D) Cardiac catheterization/EPS and angiographic medical records must include at a minimum the following information: type of procedure performed, indication for procedure, time course of procedural events, time and dose of all medications administered, fluoroscopy time, all catheter sheaths and special guide wires used, pertinent hemodynamic and/or electrophysiologic data, a

detailed summary of the procedure, and a description of the angiographic/electrophysiologic findings and clinical recommendations.

(E) A quarterly written report of QAPI findings, recommended actions, progress on implementation and supporting data shall be available for Department review.

#### 130.970: Reporting to the Department of Public Health

When requested by the Department, each hospital shall submit information regarding patient outcomes and utilization.

#### 130.975: Cardiac Catheterization Services without Cardiac Surgery Services

A hospital that operates a cardiac catheterization service and does not provide cardiac surgery services shall meet the following requirements:

(A) The hospital shall maintain a current written collaboration agreement with at least one tertiary hospital with a cardiac surgery program. The agreement shall include all of the following:

- (1) Guidelines for the selection of patients appropriate for cardiac catheterization at the hospital without cardiac surgery.
- (2) Provisions for emergency and routine transfer of patients including timely transfer of appropriate patient information. Language shall be included that describes the agreed upon cardiac catheterization image standard, to avoid redundant catheterization.
- (3) Provisions that specify that cardiac surgery staff and facilities shall be immediately available to the patient upon notification of an emergency.
- (4) Provisions that specify the responsibility for arranging transportation to the receiving hospital.
- (5) Provisions for joint quality assurance reviews.
- (6) Provisions for joint training and ongoing education of staff.
- (7) Explicit description of responsibilities of each party to the agreement.

(B) The following procedures shall not be performed in a hospital that is not approved to perform cardiac surgery:

- (1) Percutaneous coronary interventions.<sup>1</sup>
- (2) Percutaneous balloon valvuloplasty.
- (3) Myocardial biopsy.
- (4) Placement of any permanent cardiac devices other than cardiac pacemakers, defibrillators or implantable event monitors.

#### 130.980: Prerequisites to the Performance of Electrophysiology Studies (EPS)

Hospitals shall not perform intracardiac electrophysiology studies unless the hospital is licensed to provide cardiac catheterization services.

#### 130.982: Diagnostic and Interventional/Therapeutic Electrophysiology Studies

(A) Each hospital shall specifically define, based on nationally accepted standards of the American College of Cardiology/American Heart Association and the Heart Rhythm Society (HRS), the qualifications necessary for privileges to perform diagnostic and interventional/therapeutic EPS. Such policies shall ensure that EPS shall be performed by a physician board certified in cardiovascular disease who has a minimum of at least one additional year of specialized training in EPS and cardiac arrhythmias as defined by the Heart Rhythm Society (formerly known as the North American Society for Pacing and Electrophysiology (NASPE)).

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<sup>1</sup> MASS COMM Trial participating hospitals are excepted.

(1) Physicians performing electrophysiology procedures (except for those physicians who only implant pacemakers and perform no other electrophysiology procedures) must be board certified in clinical cardiac electrophysiology. Physicians who are within 12 months after completion of a fellowship in clinical cardiac electrophysiology, while awaiting board certification, may perform electrophysiology procedures under the supervision of a physician board certified in clinical cardiac electrophysiology, who performs more than 125 procedures per year, until he/she passes the board certification exam.

(2) Consistent with HRS guidelines, non-electrophysiologists wishing to implant cardioverter-defibrillators (ICDs) and cardiac resynchronization therapy (CRTs) devices must be trained in an American Council for Graduate Medical Education (ACGME) approved fellowship program and pass a competency exam offered by the International Board of Heart Rhythm Examiners.

(B) Renewal of physician privileges shall at a minimum include a review of all procedures for appropriateness, technical quality, patient outcomes and other quality assurance information developed through the Quality Assessment and Performance Improvement (QAPI) program. The review shall include an assessment of procedure volume for consistency with recommended minimum volumes in American College of Cardiology/American Heart Association and HRS guidelines, as applicable, for maintaining competency in performing procedures.

(C) A registered nurse, Nurse Practitioner or Physician Assistant trained and experienced in advanced life support, cardiac drugs, and cardiac catheterization/EPs and a technician trained and experienced in cardiac catheterization/EPs shall be present during the procedure.

(D) Physician anesthesia services shall be available on site for emergencies.

(E) Appropriate staff shall be available to ensure all electronic and mechanical equipment is regularly checked and maintained in safe working order.

(F) The following at a minimum shall be provided for the performance of diagnostic and interventional EPs procedures:

(1) fluoroscopy unit,

(2) programmable stimulator,

(3) multi-channel physiologic recorder, and

(4) resuscitative equipment.

(G) Provisions for pacing, defibrillation, and resuscitation must be immediately available.

(H) When requested by the Department, each hospital performing EPs shall submit information regarding patient outcomes and utilization.